



Testing and Certification Regulations

TÜV SÜD Group

Scope:

These Testing and Certification Regulations (TCR) apply to the TÜV SÜD Group, e.g. the following legal entities:

Company	Web site
TÜV SÜD Auto Service GmbH	www.tuev-sued.de
TÜV SÜD America Inc.	http://www.tuv-sud-america.com
TUV SUD BABT	http://www.tuv-sud.co.uk/uk-en/about-tuev-sued/tuev-sued-in-the-uk/tuev-sued-babt
TÜV TÜV SÜD Czech s.r.o.	www.tuv-sud.cz
TÜV SÜD do Brasil	www.tuv-sud.com.br
TÜV SÜD Energietechnik GmbH Baden-Württemberg	www.tuev-sued.de
TÜV SÜD Industrie Service GmbH	www.tuev-sued.de
TÜV SÜD Korea	http://www.tuv-sud.kr/kr-en
TÜV SÜD Management Service GmbH	www.tuev-sued.de
TÜV SÜD Product Service GmbH	www.tuev-sued.com/ps_regulations
TÜV SÜD PSB Pte Ltd.	www.tuv-sud-psb.sg
TÜV SÜD Rail GmbH	www.tuev-sued.de
TÜV SÜD Sec-IT GmbH	www.tuev-sued.de
TÜV SÜD South Asia	https://www.tuv-sud.in/in-en
TÜV SÜD Certification and Testing (China) Co., Ltd.	http://www.tuv-sud.cn/
TÜV SÜD Hong Kong Limited	http://www.tuv-sud.cn/
TÜV SÜD Malaysia Sdn. Bhd	https://www.tuv-sud.my/my-en

Hereinafter solely and jointly referred to as TSC (TÜV SÜD Company).



The Testing and Certification Regulations apply to:

- the testing and/or certification of products, services and projects (hereinafter collectively referred to as products)
- the auditing and certification of management systems (hereinafter referred to as system)

In as far as clients have concluded multiple contracts for obtaining a certificate (separate contract partner(s) for the service contract and the certification contract with the latter being the TSC to which the contract-relevant certification body/bodies is/are affiliated), the provisions of the TCR will apply to the contractual relationship between the “certification body TSCs” and the client.

These Testing and Certification Regulations shall replace previous versions. They will become effective April 2019 and remain valid until a new version is issued.

In case of doubt, the German version shall be authoritative for work related to Certification Bodies according to ISO/IEC 17000ff located in Germany. For all other Certification Bodies the English version shall be authoritative. Certification bodies are independent third parties that confirm the conformity of products, processes, systems or persons within the scope of certification schemes.

These Testing and Certification Regulations are governed by the law of the country of the TSC which includes the certification body relevant for the requested service.



These Testing and Certification Regulations comprise a number of modules; in general module A applies to all TSC; the remaining modules apply as appropriate and may amend, replace or denote as not applicable any regulations in other modules.

In the context of C-modules any references to the certification body or TSC shall be construed as references to the certification body concerned. If there are any conflicts between the respective C-module and other sections of this document the respective C-module shall take precedence.

The full version of the Testing and Certification Regulations covers the Modules A, B1, B2 and C1 to C6.

For certain areas combinations of particular Modules are available.

Contents	Page
Module A) General regulations	4
Module B1) Special regulations for product testing and certification	15
Module B2) Special regulations for management system auditing and certification	19
Module C1) Special regulations and conditions for the field of medical devices, TÜV SÜD Product Service GmbH (TÜV SÜD PS)	25
Module C2) Special regulations for the auditing and certification by TÜV SÜD Management Service GmbH (TÜV SÜD MS)	29
Module C3) Special regulations for TUV SUD BABT (TÜV SÜD BABT) certification	37
Module C4) Special regulations for TUV SUD America Inc. (TÜV SÜD America) product testing and certification	39
Module C5) Special regulations for TÜV SÜD PSB Pte Ltd (TÜV SÜD PSB)	41
Module C6) Special regulations for TÜV SÜD South Asia	42



Module A) General regulations

A-1. General

A-1.1 These Testing and Certification Regulations apply to tests, audits, conformity assessment procedures as per EC Directives and EU Regulations, or on basis of other appointments as well as all other certification activities carried out by TSC. The services offered by TSC also include information on normative requirements or approval procedures.

The client knows that to ensure independence, impartiality and objectivity, the certification body cannot combine the testing and certification services that form the subject matter of the contract with consulting services regarding the subject matter of testing and/or certification.

The client undertakes to inform the certification body without delay of any consulting services by TSC or a TSC affiliated company received by the client.

Any jeopardizing of the certification body's independence, impartiality and objectivity on the grounds of consulting services will entitle TSC to terminate this contract without notice for important reasons as set forth in Section A-1.9 II.

A-1.2 On issue of the first certificate, the certificate holder automatically becomes a TÜV SÜD certification-system partner and remains partner as long as at least one certificate is valid. A certificate only becomes valid after all financial and technical requirements in connection with the test/audit and product/system certification have been fulfilled. If a certificate is awarded subject to certain requirements, the certificate holder undertakes to satisfy these requirements within the defined deadlines. If the requirements are not fulfilled within the defined deadlines, the certificate will be deemed withdrawn on expiry of said deadlines and will have to be returned by the certificate holder to the issuing TSC without delay.

A-1.3 Prior to placing an order, the client shall provide TSC with the name of any other organization that tested/audited/certified the same product or system in a similar way or is in the process of doing so. With each order the client agrees to accept the current version of these Testing and Certification Regulations as part of the contract. Existing contractual relationships are governed by the respectively valid versions of these Testing and Certification Regulations.



The currently valid versions of these Testing and Certification Regulations are available at the TSC of the relevant Certification Body or will be provided free of charge on request.

- A-1.4 The Certification Body of the relevant TSC evaluates the documents submitted by the testers/auditors. It decides whether a certificate is to be issued and handles disagreements/appeals concerning certification. Complaints management procedures have been established for each certification process.

Appeals and complaints shall be addressed directly to the Certification Bodies of the respective TSC. The Certification Bodies maintain documented appeals and complaints management procedures. A description of these procedures is made available to the public.

The Certification Body will forward to the certified clients in question any complaints about certified products or systems received by TSC within an appropriate period of time.

- A-1.5 Certificates, certificates of conformity, test certificates based on EC Directives and EU Regulations, standards or other criteria always relate to the version of the relevant directives, regulations, standards or other criteria valid on the date of issue of the certificate.

The Certification Body only issues a certificate or other attestation if the product or system at the time of certificate issue fulfills all certification-relevant legal requirements, applicable standards, and other certification-relevant criteria. The date on which the order is placed and/or the contract concluded is irrelevant in this regard.

A granted certificate makes no statement concerning the marketability of a certified product.

The certificate holder must at all times reference the pertinent annexes of the certificate. The certificate (and any duplicate certificates) is not transferable and shall remain the property of TSC.

Certificates only relating to EC Directives and EU Regulations do not entitle the holder to use a TÜV SÜD certification mark.

Any CE marking that may prove necessary falls solely under the responsibility of the persons indicated in the relevant directives and regulations.



- A-1.6 The client shall ensure that auditors/representatives of the authorized bodies (e. g. regulatory authority, accreditation body or certification scheme owner) are entitled to participate in “observed audits” on the business premises of the client/manufacturer and/or their subcontractor/supplier.
- A-1.7 Where on-site activities (e. g. audits, inspections) conducted by TÜV SÜD personnel require personal protective equipment, TÜV SÜD and the client shall agree upon supply of such equipment in advance of any visit.
- A-1.8 If, in addition to an electronic or other copy, a hardcopy of the test/audit report is prepared and transmitted to the client, the hardcopy will prevail and be legally binding in case of conflict.
- A.-1.9 Each certificate is subject to the existence of a valid certification contract/order.

The certification contract/order/membership in the certification system may be terminated in whole or in part, if the individual contractual regulations, the respective guidelines/rules/procedures, or the guidelines/regulations of the Certification Bodies or other authorized bodies (e. g. authorities, accreditation bodies or certification scheme owner) do not define other periods of notice:

I. by termination **without cause**

- a. for system certifications: with three (3) months notice to the next scheduled audit due date (for the surveillance or the recertification audit respectively) by the certificate holder or TSC.
- b. for product certifications: with two (2) months notice to the end of the respective calendar year by the certificate holder or with one (1) year notice to the end of the respective calendar year by TSC.
- c. System certification based on EC Directives and EU Regulations are handled by TSC according to I.b.

II. by termination **for cause** at the terminating party’s choice with or without notice, in particular (but not only) if the certificate issued on the basis of the certification contract/order may be withdrawn, revoked or restricted according to the following regulations set forth in paragraphs A-2.1 – A-2.3..

Terminations have to be made issued in writing to be effective.



If the validity of a certificate ends or if the certificate is revoked, withdrawn or expires irrespective of the reason, the underlying certification contract/order for this certificate will also expire automatically without requiring separate termination. This does not apply if the contacting parties have agreed on continuing the contractual relationship prior to its automatic expiry.

In case where the holder's last remaining certificate is no longer active, the certificate holder's membership in the certification-system of TÜV SÜD is suspended.

The expiry of the certification contract/order will not affect any existing claims against the client, e.g. unsettled receivables. All costs and expenses for upcoming surveillance or auditing/testing of the certified system or product already incurred can be claimed.

The requirements of these Testing and Certification Regulations will apply during the term of the certification contract/order and for three (3) years thereafter (grace period). If only part of the certification contract/order is terminated, the grace period will also apply to the terminated part.

A-1.10 Should any individual provision of this Testing and Certification Regulations or any part of any provision be or become void or unenforceable, the validity of the remaining Testing and Certification Regulations hereof shall remain unaffected. In such case the void and/or unenforceable provisions shall be replaced by corresponding provisions coming as close as possible to the sense and spirit and purpose of the void and/or unenforceable provision.

A-1.11 The certificate holder shall ensure that the Certification Body can inspect the manufacturing and business premises listed on the certificate and the relevant warehouses of their representatives, importers and branches at any time during standard business hours and without prior notice at the certificate holder's expense. Certificate holders must also ensure that the Certification Body can take the required number of samples of certified products for testing purposes free of charge, even if the manufacturing and business premises are not their own. The inspection report will be provided to both the manufacturing site representative and the certificate holder.

A-2. Expiry, withdrawal, revocation, restriction or suspension of certificates

A-2.1 A certificate expires automatically or is deemed to be withdrawn if

A-2.1.1 the indicated period of validity expires or if the contractual basis for use of the certificate and/or certification mark otherwise ceases to apply;



- A-2.1.2 insolvency proceedings are opened over the certificate holder's assets or the opening of such proceedings is refused for lack of assets and the certificate holder fails to inform the responsible certification body in writing and within one month of its application for insolvency proceedings;
- A-2.1.3 the certificate holder permanently discontinues business operations without a legal successor;
- A-2.1.4 the requirements (e.g. of a regulatory authority, accreditation body or certification scheme owner, codes of practice etc.) on which the certificate is based have changed and the certificate holder is unable to demonstrate within a defined time period at the certificate holder's expense that the product or system conforms to the new requirements through TSC re-testing or re-auditing;
- A-2.1.5 the underlying (basic) certificate becomes invalid;
- A-2.1.6 the certificate holder is obliged to withdraw the product/certified service from the market;
- A-2.1.7 the product or system has been inadvertently assigned to the wrong basis of evaluation under the scheme rules, e.g. an incorrect class as per the relevant EC Directive and EU Regulation on which conformity assessment is based;
- A-2.1.8 defects or nonconformities are detected in the products or systems; products fail to conform to the certified samples or key prerequisites pertaining to the certified product/system are not or no longer fulfilled.
- A-2.2 The Certification Body in the respective TSC is entitled to suspend, withdraw or revoke a certificate at its own discretion with or without notice, in particular if
- A-2.2.1 further use of a certification mark/certificate is no longer justified, i.e. not or no longer meaningful within the market context or is prohibited by law; in such cases, TSC will provide an alternative certification mark, if possible;
- A-2.2.2 the certificate holder engages in, initiates or tolerates
- misleading or otherwise unacceptable advertising, in particular with the certification mark, the certificate or the test report,
 - misuse of certificates, certification marks or test reports, or
 - violation of legal provisions when marketing a product tested by TÜV SÜD.
- A-2.2.3 the certificate holder fails to pay outstanding invoices within 4 weeks to TSC, despite receiving written reminders to that effect;



A-2.2.4 the certificate holder files for insolvency or similar proceedings under foreign law outside of Germany or the opening of such proceeding is rejected for lack of assets;

A-2.2.5 the certificate holder violates these Testing and Certification Regulations and/or the related part of the contract/order, unless such violation is insignificant in nature or represents only minor negligence;

TSC is entitled but under no obligation to grant the certificate holder a period of grace to remedy the violation.

A-2.2.6 the relevant Certification Body forms the opinion that

- the certified product or system does not or no longer comply or no longer complies with the underlying certification requirements or standards, or
- fails to fulfill its purpose as defined by the manufacturer, or
- is exposing users, operators or third parties to considerable risks, or
- fails to adapt the product or system to the applicable version of the relevant standard or certification requirement within the period of time allowed to the certificate holder by the Certification Body; or
- the certificate holder is in violation of any certification-related conditions/obligations.

A-2.2.7 the certificate holder makes incorrect statements to TSC or withholds from TSC important facts that are relevant for certification.

A-2.2.8 it becomes evident after certificate issue that the certificate holder failed to fulfill the certification requirements from the outset.

A-2.2.9 the certificate holder objects to changes in these Testing and Certification Regulations and/or a relevant part of the contract/order (e.g. the relevant current rates and fees) within a 6-week period of appeal after such amendments have come into effect;

A-2.2.10 inspection or auditing of facilities or product testing is not made possible or the products or documents are not made available within the specified time. This also applies if follow-up-services, surveillance measures or audits cannot be carried out within a timeframe of 4 weeks (unless otherwise specified by the Certification Body) despite a written request to this effect or if nonconformities are not eliminated within the agreed period through appropriate corrective actions.

A-2.3 Certificates can also, be restricted or suspended with regards to time and content for the reasons noted above (A-2.1 and A-2.2).



A-2.4 The Certification Body of the respective TSC is entitled to publish details of the expiry, withdrawal, revocation, restriction and suspension of a certificate. Continued advertising or other use of the certificate/certification mark or the name of TSC is prohibited in all such cases. A certificate that has expired, has been withdrawn, or has been revoked shall immediately be returned to the Certification Body and/or destroyed upon the Certification Body's written request. License fees paid in advance shall not be reimbursed; those not yet paid shall be paid in full.

A-2.5 Apart from cases of willful intention and gross negligence, TSC shall not be liable for any disadvantages arising for the client from non-issue, expiry, withdrawal, revocation, restriction or suspension of a certificate.

A-3. Use of certificates, certification marks and test reports in business transactions

A-3.1 Granting rights of use

During their certificates' terms of validity clients are entitled to use their certificates in their business transactions as set forth in these Testing and Certification Regulations. If the respective certification criteria and procedures provides for the issue of a certification mark, clients will also be granted the limited, non-exclusive right to use the certification mark in their business transactions and in particular their advertising during the period of validity of the underlying certificate. In this context, clients may only use the certification mark assigned to the respective certification. The right of use will expire on expiry, withdrawal, revocation, restriction or suspension of the underlying certificate.

A-3.2 Terms of use of certification marks and certificates

A.3.2.1 In the case of certifications that are not required by law, advertising must make clear that certification is voluntary and must reference the certification standards and the owner of said certification standards.

A-3.2.2 Certification marks and certificates may not be misused or used in a misleading manner that may jeopardize the trust of the public in the TSC's certification marks or certificates. The role of the TSC as an independent third party shall not be compromised by the use and visual presentation of certification marks.



A-3.2.3 A certificate or mark referring to a management system may only be used to promote the system concerned. A product certificate or product mark (in as far as a mark is approved) may only be used to promote the certified product.

The use of certificates and/or certification marks must not give the impression of certification applying to activities outside the scope of certification.

A-3.2.4 Product-related advertising using a certification mark is not permissible in cases where only a certificate of conformity or management system certificate has been issued.

A-3.2.5 Where certification marks or certificates refer only to certain partial aspects of a product or system, advertising must not give the impression of certification of the entire product or system.

A-3.2.6 Full responsibility for correct use of the certificate and/or certification mark and for the correctness of all statements about the certified system / product rests with the certificate holder. In the case of product certification this also applies to correct use/advertising by the customers of the certificate holder.

A-3.2.7 It is recommended that clients, when using certification marks and certificates in their advertising, take steps to ensure that the target groups addressed by advertising can inform themselves easily, adequately and transparently of the content of the TSC services underlying the certification marks or certificates.

A-3.3 **Requirements regarding the visual presentation of certification marks**

A-3.3.1 Clients may use certification marks only and may under no circumstances use the TÜV SÜD logo ("TÜV SÜD – Octagon", logo see headline) or the slogan of the TÜV SÜD Group (at present: "Choose certainty. Add value.").

A-3.3.2 Neither the content nor the design of the certification mark provided by TSC may be changed. It must be recognizable as certification mark and its size must be clearly smaller than that of the company logo of the client/certificate holder. The information included in the certification mark must be clearly legible even if the certification mark is displayed at reduced size.



A-3.3.3 The certification mark must stand alone and may not be associated or combined with any other element (e.g. the client's company logo, statement or graphics). The use of the certification mark in particular must not give the impression that the client/certificate holder or its employees are members of the TÜV SÜD Group or that the certification mark is the client's trademark/customer logo.

A.3.4 Use of TSC test reports

Unless expressly approved beforehand in writing by the relevant certification body of the relevant TSC or where use of the report is an integral part of the underlying certification procedure or disclosure is required on the basis of legal, regulatory or accreditation-related requirements, the following shall apply:

- Reports by TSC may not be reproduced in part or in full.
- The use of, or reference to, reports or names of TSC for advertising purposes is not allowed.

If test reports, benchmark test reports audit reports or other reports are used with the approval of the TSC, the client shall not complement said reports by adding any statements or interpretations that go beyond the reports' actual contents. Clients in particular shall not add any distorting or misleading statements or interpretations that could give rise to doubts in the impartiality of TÜV SÜD. Clients must ensure at all times that the test results of the TSC are reproduced correctly and not distorted.

The same applies to communication activities, advertisements, confirmations, communications, sales collaterals etc in digital, audio and print media.

In cases in use of the reports prepared by TSC is approved, said reports may only be quoted verbatim and with their complete wording, giving the date of issue.

TSC reports may never be used to claim or imply that TSC particularly recommends the product or system to customers.

A-3.5. Consequences of impermissible use

The client undertakes to indemnify TSC or the respective TSC certification body at first request against all claims by third parties arising as a result of the client's use of the certification mark, certificate or TSC report contrary to the terms of this contract. The same applies to all claims by third parties against TSC /TSC certification body arising as a result of advertising statements made by the client.



A-4. Publication of certificates, certification marks and test reports

TSC can publish the names of the certificate holders, tested products, audited systems, etc. for consumer information or if required by the certification procedure. TSC shall be entitled to grant authorized bodies (e.g. authorities, accreditation bodies or certification scheme owners) direct access to the certification-relevant documentation at any time.

All further information about clients, certified products and systems are subject to confidentiality unless the disclosure of such information is requested by court or an authorized body or otherwise mandatory by law or for the certification procedure. This obligation of non-disclosure applies equally to all employees and agents of TSC.

A-5. Retention of test samples and documentation

As far as clients are in possession of test samples and pertinent documentation, they must retain them for a period of ten (10) years after expiry of the certificate or after the last product is placed on the market area covered by the certificate, whichever is the longer.

System certification documentation shall be retained for the term of validity of the certificate plus a minimum of three (3) years.

All other legal provisions extending beyond shall remain unaffected.

Claims for damages against TÜV SÜD or TSC shall be excluded, in particular if clients fail or are unable to provide a test sample/document returned to or retained by them in unchanged condition.

A-6. Violation of Testing and Certification Regulations

TSC is entitled to claim payment of a contractual penalty of up to EUR 250.000 in the case of culpable violations of these Testing and Certification Regulations by the certificate holder. This applies specifically if a product labeled with the certification mark is offered for sale or marketed prior to the issue of the certificate, if unauthorized advertising takes place or if a certificate or certification mark is misused.



The certificate holder is liable for costs charged to TSC by authorized bodies (e. g. regulatory authority, accreditation body or certification scheme owner) or costs directly incurred by the Certification Body or the test laboratory resulting from culpable violation on the part of the certificate holder, in particular violation of these Testing and Certification Regulations. This applies in particular if TSC's activities were the result of instructions issued by a supervisory authority or similar instructions and if such instructions proved to be justified.



Module B1) Special regulations for product testing and certification

B1-1. Testing

- B1-1.1 The client shall submit a test order to TSC and supply the required test samples and documentation free of charge. TSC shall, at its own discretion, carry out the tests either in their own test laboratory or externally, and prepare a summary report.
- B1-1.2 Following the test, TSC shall dispose of the test samples for a flat-rate charge per sample or, at the clients' express request, return them to the latter at their expense. TSC will not store test samples but may require the client to do so. If a test is interrupted for more than one month, TSC may also return the sample or store it for a flat-rate charge for each month or part-month that elapses up to continuation of the test.
- B1-1.3 TSC is entitled to make the test file and, if necessary the test sample, accessible to authorized bodies (e. g. regulatory authority, accreditation body or certification scheme owner). Any agreement to the contrary is invalid.
- B1-1.4 TSC shall not assume any liability if test samples are lost or damaged either in the course of testing or due to burglary, theft, lightning, fire, water etc.
- B1-1.5 No consulting services will be supplied on product development or management-system establishment.

B1-2. Certification

After successful completion of product testing, TSC will award a certificate either with or without authorization to use a certification mark. If product certification does not include manufacturing surveillance, the product must not be labeled with a certification mark. The following regulations apply to product certification that includes the issue of a certification mark:

- B1-2.1 In addition to a positive product testing result, initial inspection of the manufacturing site must not raise any objections. Continued use of the certification mark will depend on regular inspections (follow-up-service, see below).



- B1-2.2 The certificate holder shall only use the certification marks defined in the certificate for the specific models listed on the certificate.

The certificate holder shall be responsible for controlling the use of the certification mark and ensure that the certification mark is only used in conjunction with the certificate holder's identity and the specific certified model number.

The certificate holder shall not transfer the certificate rights to third parties.

Should a product certificate become invalid, the products listed on the certificate shall not be made available on the market for the first time using the certification mark or in case of CE-marking with the notified body number.

Holders of withdrawn or revoked certificates must in addition either remove the certification mark from all accessible products or destroy the products and enable the Certification Body to verify these measures.

- B1-2.3 TSC certification marks may only be used for products that conform to the successfully tested type and the specifications included in the test report or supplementary agreements. The required documents (e. g. certificate of conformity, operating and assembly instructions) are to be enclosed with the product in the appropriate language of the country of destination.

- B1-2.4 Additional characteristics for individual certification marks

If a product is manufactured at several manufacturing sites with different qualifications (e. g. with or without ISO 9001), the qualification level of the respective manufacturing site may only be used if different designations are given to the models. Otherwise only the level of qualification which applies to all manufacturing sites may be used for advertising.

- B1-2.5 Holders of certification marks must constantly monitor the manufacturing of products that have been awarded the mark to ensure conformance to test requirements. They must also carry out the specified tests and inspections, document any complaints in connection with certified products and the correction of nonconformities. The Certification Body must be immediately notified of any changes made to the products, recalls or safety related incidents after certification. If the certificate concerned is to be maintained, the Certification Body may request the manufacturer to prove compliance with standards and/or codes of practice or may require an additional test to be carried out by a qualified test laboratory.



- B1-2.6 As a minimum requirement, every product must be identified by a label clearly indicating the name of the manufacturer or importer and type designation, so that the identicalness of the approved type with the serially manufactured product can be ascertained. If a product submitted for testing does not satisfy the test requirements and if products corresponding to this test sample have already been distributed for sale or have been the subject of a certification mark misuse, the modified test sample may only be certified if it bears another type designation.
- B1-2.7 Inspection of manufacturing sites in the case of certificates including authorization to use a certification mark (follow-up-service), market surveillance:
- B1-2.7.1 In order to ensure maintenance of the product characteristics on which a certificate has been based, the Certification Body will regularly inspect manufacturing and testing facilities as well as quality assurance measures at the certificate holder's expense. Alternatively, for certification including the right to use a mark, random checks based on modules of the Council Decision 768/2008/EC may be agreed prior to issue of the certificate. If the system of the respective manufacturing site has been certified by TÜV SÜD, the follow-up-service may also be incorporated in the surveillance/re-certification audit pertaining to the system.
- To ensure production quality, additional pre-shipment inspection may be agreed, in which samples from the products to be shipped are checked for conformance to the tested and certified type.
- B1-2.7.2 The certificate holder shall immediately inform the Certification Body of any relocation of a manufacturing plant, transfers of manufacturing plants to another company/company owner or changes in the manufacturing process that may affect the certified product. In these and other special cases, the Certification Body may demand that the product is identified by a predefined inspection mark, in addition to the certification mark, so that products from different periods of manufacturing can be identified. Should there be a change in the manufacturing site, TSC must inspect and approve the new production facility before the products manufactured there can be labeled with a certification mark. The holder shall inform the Certification Body of any changes to the holder details.
- B1-2.7.3 The Certification Body is entitled to take samples of products identified by a certification mark from the market for testing purposes. If the certificate requirements are not satisfied, e. g. because of unauthorized modifications that have resulted or may result in certificate withdrawal, the certificate holder shall bear the costs of re-testing/inspecting the product and/or the manufacturing site.



B1-2.7.4 The certificate holder shall inform the Certification Body immediately of any damage or other events arising from certified products.

B1-2.8 In addition to an existing (basic) certificate further certificates may be issued

- a. For the same (basic) certificate holders if they seek to certify a product under another name than that appearing on the (basic) certificate.
- b. For certificate holders differing from the (basic) certificate holders, if they also seek to certify a product under another or same name than that appearing on the (basic) certificate. Prerequisite is the approval of the (basic) certificate holders and their confirmation of equality of design of the product with that from the (basic) certificate.

The content and validity of such certificates shall be dependent on the (basic) certificate.



Module B2) Special regulations for management system auditing and certification

B2-1. General

TSC carries out management system (hereinafter referred to as "system") auditing, verification and certification in the non-regulated and regulated area, including according to EU Directives and EU Regulations.

TSC does not perform consultancy services relating to management system establishment, including customer-specific training and internal audits on the subject matter of the certification.

B2-2. Preliminary system assessment, pre-audit

On request, TSC offers the following services which can also be independent of a certification procedure:

B2-2.1 Based on management system documentation, areas of concern in the description of the system are pointed out in a preliminary assessment as compared with the requirements of the respective legal basis or standard. The client receives a report on the results of the assessment.

B2-2.2 The aim of the pre-audit, the on-site and total scope of which is defined jointly with the client, is to draw attention to areas of concern in the system. The auditor informs the client of the results in a closing meeting; if requested, TSC prepares a pre-audit report. Only one (1) pre-audit may be carried out.

B2-3. Certification procedure

B2-3.1 Preparation

B2-3.1.1 Informational meeting

At the client's request, the following points can be discussed in advance:

- objective, benefits and prerequisites of certification
- steps in the certification procedure with respect to contents and time
- legal basis, standard governing the audit, audit scope
- cost estimate



B2-3.1.2 Preparation for certification audit

After the client has accepted in writing the quotation submitted by TSC, the client's management appoints an Audit Representative, who is responsible for the certification procedure; TSC informs the client of the auditors assigned to the audit (audit team or lead auditor). Requirements outlined in the applicable standards and regulations pertaining to unauthorized consultancy on the part of auditors are observed. The client has the right to reject auditors.

In addition and in as far as there are no conflicting legal regulations, e. g. regulations under the data privacy law, clients can request appropriate background information on each member of the audit team.

B2-3.2 Certification audit

An initial certification audit is carried out in (2) stages (stage 1 and stage 2 audit).

The client shall ensure that appropriate staff members are available to answer questions; clients grant auditors access to the respective units of the company and allow them to review all system-relevant records.

B2-3.2.1 Review and evaluation of management system documents / stage 1 audit

Clients shall provide the Certification Body with all requested management system documentation concerning their systems (manual and, if necessary, further documents such as documented procedures, work test instructions, records, etc.) for review and assessment of compliance with the applicable Directives, Regulations and Standards. If the system is already certified by another body to the same or an appropriate standard then the client shall include a copy of the certificate with any scoping information, and details of the findings of the previous audit.

The Certification Body shall

- review the management system documentation
- determine readiness for the stage 2 audit
- review key performance or significant aspects regarding the scope and operation of the management system
- collect necessary information regarding the scope and the related statutory and regulatory requirements of the client's operation
- plan the certification (stage 2) audit, including confirmation of audit team requirements



- check whether internal audits and management review are being performed and that the level of implementation substantiates the client's readiness for the stage 2 audit

Based on the results of the stage 1 audit, the Certification Body assesses whether the level of management system implementation is sufficient for conducting a stage 2 audit and plans the process and priorities of the stage 2 audit. The details of the stage 2 audit will be agreed with the client.

Where required by court order or other authorized bodies (e.g. regulatory authorities, accreditation body or certification scheme owner), TSC may request product samples in order to verify the implementation of the management system. Additional costs related to such additional testing shall be paid by the client.

The Certification Body documents the findings of the stage 1 audit and notifies the client thereof, including information about identified areas of concern which may be classified as nonconformities in the stage 2 audit.

The interval agreed between the stage 1 and stage 2 audit, will give the client sufficient time to eliminate any identified areas of concern (weaknesses).

B2-3.2.2 On-site certification audit / stage 2 audit

Prior to the stage 2 audit TSC shall provide the client with an audit plan, which has been agreed with the client. During the audit, clients demonstrate practical implementation of their documented procedures, while the auditors check and evaluate system effectiveness on the basis of the agreed legal provisions, standards or other criteria.

B2-3.3 Certification

If all requirements of the applicable standard(s) are satisfied and all legal and official regulations observed, the Certification Body will issue a certificate, generally with a three (3)-year period of validity from the date of the certification decision, unless specific directives/schemes, regulations, standards or individual arrangement in the certification contract require other periods of validity.

B2-3.4 Surveillance audit

Surveillance audits carried out in the company at regular intervals (generally annually) with acceptable results are a prerequisite for continued certificate validity.



The first surveillance audit must be carried out within twelve months of the last day of the stage 2 audit at the latest, provided no other deadlines have been determined in specific regulations. TSC shall be entitled to carry out audits at short notice or unannounced (ad-hoc) audits at the expense of the certificate holder. To prepare for the surveillance audit, the valid management manual and a list of all effected amendments must be submitted to the Certification Body upon request. In the surveillance audit, the auditor checks selected management system elements/processes to ensure that the management system continues to fulfill the requirements. The auditor will prepare a report.

B2-3.5 Further surveillance activities

Further surveillance activities may include:

- Enquiries regarding certification aspects addressed by the Certification Body to certified clients
- Assessment of client information about their operations (e.g. advertising materials, web pages),
- Requests addressed to clients to provide documents and records (hard copies or electronic media), and
- Other means of monitoring the performance of the certified client.

B2-3.6 Re-certification audit

Re-certification audits are carried out well in advance of certificate expiry to allow for continuous certification. If such a re-certification audit has been carried out successfully, a renewal certificate may be issued. Re-certification audits check overall system effectiveness by means of random sampling. To prepare for the audit, the valid management manual and all major amendments effected must be submitted to the auditor/audit team. In cases involving significant changes to the system, a stage 1 audit may first be required.

B2-3.7 Nonconformities

After audit completion, TSC informs the client of the audit result in a closing meeting and an audit report. Nonconformity reports are countersigned by the Audit Representative. The client will document the required correction and corrective action. In the case of nonconformities one (1) re-audit is possible; the costs being based on the time needed (current daily rate). This includes any necessary verification of corrective actions documented in the nonconformity report.



If during the audit nonconformities become evident that are so serious that certificate award appears unrealistic even after reasonable corrective action, TSC informs the client of the termination of the certification audit and recommends that the audit should be continued as a pre-audit. In such cases, TSC will charge the costs incurred up to audit termination (including report).

B2-4. Supplementary contractual terms

B2-4.1 As far as possible, the Certification Body is obliged to ensure that clients use certification correctly in advertising.

The Certification Body reviews and evaluates complaints by third parties, issues causing concern or changes in the client's organization that comes to its knowledge. It informs the certificate holder of substantial changes to the certification and surveillance procedure as well as of any changes in the standards which are relevant for certification.

B2-4.2 The client shall satisfy all reasonable requirements pertaining to certification and supply all information required for auditing.

Certificate holders shall inform the Certification Body immediately, but at the latest within one (1) month in writing of all relevant changes in their systems and about any modifications in company structure/organization that affect the compliance of the management system, or any other significant events affecting compliance with the requirements for certification.

These changes may include but are not limited to:

- legal or organizational status;
- commercial status or ownership;
- organization and/or management (including individual changes in key personnel);
- contact address and the addresses of sites;
- scope of operations under the certified management system, and
- significant changes to the management system and processes including planned changes if requested by the Certification Body or scheme.

In addition, certificate holders shall document internal and external complaints relating to their management systems as well as implemented corrective action and provide such information during the audit.



The Certification Body will review the changes and advise the certificate holder of any action required to continue the certification.

Despite the fact that TSC normally informs the certificate holder of due surveillance/re-certification audits, it is also the responsibility of the certificate holders to request such audits at least three (3) months before they become due within the 12-month-cycle in order to maintain the validity of a certificate.

- B2-4.3 Changes in the standards, underlying codes of practise or other regulations shall apply – under consideration of transition periods – as binding contractual basis.

The number of auditor days cited in the quotation shall apply subject to the approval of the Certification Body.

- B2-4.4 Integrated management systems must allow specific aspects of individual systems to be identified.

- B2-4.5 The Certification Body may make information about issued, withdrawn, suspended or revoked certificates available to the public.



Module C1) Special regulations and conditions for the field of medical devices, TÜV SÜD Product Service GmbH (TÜV SÜD PS)

(These terms and conditions complete or amend modules A and B as follows:)

C1 -> A Module A

C1-1. -> A-1.4 The following provisions are inserted: All documentation for conformity assessment shall be in English and/or in German.

C1-2. -> A-1.11 The following provisions are inserted as additional section A-1.11:
The manufacturer or the authorised representative shall inform the notified body of every relevant vigilance information, especially field safety corrective action, field safety notice and trend report.

The manufacturer or the authorised representative shall provide the notified body with a risk analysis for every field safety corrective action at the same time as it is provided to the national competent authority. In addition, the manufacturer or the authorised representative is obliged to provide the notified body with a final vigilance report.

C1-3. -> A-2.2 is replaced as follows: The Certification Body shall be entitled to restrict, suspend, revoke or withdraw a certificate at its own choice with or without notice, taking Section C1-5. -> A-2.6 into account. This applies in particular, if:

C1-4. -> A-2.4 is replaced as follows: Certificate expiries, revocations, withdrawals, restrictions and suspensions may be published; in such cases, continued advertising or other use of the TÜV SÜD PS certificate/mark or TÜV SÜD PS' name shall be prohibited. If certificates are governed by the Directives/Regulations on active implantable medical devices, medical devices or in-vitro diagnostic medical devices, the relevant products must no longer be sold under ID No. 0123 with immediate effect, unless the Certification Body has given its written permission to do so for a certain defined period. An expired, revoked or withdrawn certificate must be returned to the Certification Body. Licensing fees paid in advance will not be reimbursed; in the above case, all outstanding fees must be paid in full.

C1-5. -> A-2.5 The following paragraphs shall be inserted as further points after A-2.5:



- C1-6. -> A-2.6 Unless a hearing is impossible in view of the urgency of a decision or fails to take place within 14 days after written notification, the certificate holder must be heard, before a decision is made concerning a measure as per C1-2. -> A-2.2. However, on a case-by-case basis, an individual period may be defined for clarification.
- C1-7. -> A-2.7 TÜV SÜD PS adheres to its notification duties as per MPG (Medical Devices Act) § 18 (3), as per MDR (Medical Devices Regulation) Article 57 and IVDR (In Vitro Diagnostics Regulations) Article 52.
- C1-8. -> A-4 is replaced as follows: Clients must retain any test samples and pertinent documents in their possession for a period of minimum 10 years (15 years in case of implantable medical devices) after certificate or marketing-approval expiry.

Documents pertaining to the certified system or product must be retained for at least 10 years (15 years in case of implantable medical devices) after expiry of certification.

Any legal regulations exceeding the above requirements (e. g. for certificates as per EC Directives and EU Regulations) shall remain unaffected by the above provision.

TÜV SÜD PS may, in particular, not be held liable for damage or loss, if clients fail or prove unable to provide the test sample/document returned to or retained by them in its original state.

C1 -> B1 Module B1

- C1-9. -> B1-1.1 is replaced as follows: The client shall commission TÜV SÜD PS to carry out the required tests and shall provide the latter with the necessary test samples plus pertinent documentation to TÜV SÜD PS free of charge. TÜV SÜD PS will carry out the tests in-house in its laboratory or, after approval by the client, externally, and prepare a test report.

C1-10. -> B2-2 is not applicable

C1-11. -> B2-3.4 is supplemented as follows:

QM Certificates issued under EC Directives/regulations (for quality management systems) may be valid for a maximum of five (5) years after certificate issue/certification decision, provided regularly required (at least on annual basis) surveillance audits are carried out at the company with positive results.



For the maintenance and renewal of such certificates periodic performance of an audit as re-certification audit (with regard to content and duration) is necessary at least every 5 years.

C1-12. -> B2-3.4 is supplemented as follows:

Unannounced audits may be conducted without specific cause at the expense of the certificate holder.

Such unannounced audits may also be conducted on the premises of critical subcontractors and/or crucial suppliers. They may be conducted in addition to, or instead of a regular audit. The certificate holder shall ensure through contractual arrangements with its subcontractors and/or suppliers along the supply chain that TÜV SÜD PS has access to their premises at any time.

Within the context of such unannounced audits, but also during surveillance audits, TÜV SÜD may check and test recently produced adequate sample(s), preferably taken from the ongoing manufacturing process at the expense of the certificate holder.

Transport, insurance, logistics, customs etc. of the sample(s) to TÜV SÜD PS shall be arranged by, and at the expense of, the certificate holder.

If visas are needed for unannounced audits, the certificate holder shall provide to TÜV SÜD PS with invitations to visit critical subcontractors or crucial suppliers at any time (invitations which leave the date of signature and the date of visit blank to be filled in at a later date by TÜV SÜD PS).

C1-13. -> B2-3.6 is supplemented as follows:

An on-site audit shall be carried out in advance of expiry of the EC certificate to allow for continuous certification and may be carried out as an off site audit. If such an audit has been successfully carried out, a new certificate may be issued.

The application for extension of the certificate shall be submitted 6 months prior to expiry of the certificate.

C1-14. -> B2-3.7 second paragraph is not applicable



C1-15. The Certification Body must be informed in due time of any planned change to the approved device type or of its intended purpose and conditions of use. Additionally, the Certification Body must be informed about planned changes that could affect the safety and performance of the device or the conditions prescribed for use of the device. The manufacturer shall inform the Certification Body as well of any planned change with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process.

In case that the manufacturer uses derivatives of tissues or cells of human origin the manufacturer must notify the Certification Body about any planned change with respect to non-viable tissues or cells of human origin or their derivatives incorporated in a device, in particular relating to their donation, testing or procurement.

All information related to any planned change submitted to the Certification Body must be adequately relevant and defined. The Certification Body is entitled to ask for additional information relating to such change at any time.

C1-16. The manufacturer shall inform in due time the Certification Body of any plan for relevant changes to the quality management system. All information related to any planned change must be adequately relevant and defined. The Certification Body is entitled to ask for additional information relating to such changes at any time.



Module C2) Special regulations for auditing and certification by TÜV SÜD Management Service GmbH (TÜV SÜD MS)

(These terms and conditions supplement or amend modules A and B as follows:)

C2 -> B2 Module B2

C2-0. -> B2 The number of auditor days and other accreditation-relevant requirements cited in the quotation shall apply subject to the approval of the Certification Body.

C2-1. -> B2 Additional terms and conditions of auditing, verification and certification apply to:

C2-1.1 -> B2 VDA 6.x: VDA volume 6 "Basis for Quality Audits" and VDA volumes 6.1, 6.2 and 6.4. VDA volume 6 sets forth the requirements, rules and processes of audits carried out between automobile manufacturers and suppliers and third-party audits carried out by certification bodies and must be complied with by all parties involved. Other applicable documents supplementing the VDA 6.x volumes are the SI (sanctioned interpretations) published on the website of the VDA-QMC www.vda-qmc.de.

C2-1.2 -> B2 ISO/TS 16949: The "Automotive certification scheme for technical specification ISO/TS 16949" is binding on all IATF-recognized certification bodies and must therefore also be complied with by every client aiming for ISO/TS 16949 certification. Other applicable documents supplementing the Automotive certification scheme for technical specification ISO/TS 16949 are the SI (sanctioned interpretations) published on the website of the IATF www.iatfglobaloversight.org.

C2-1.3 -> B2 ISO 9001 and 14001: Applicable mandatory documents of the International Accreditation Forum (IAF): MD 1:2007 (Certification of Multiple Sites Based on Sampling), MD 2:2007 (Transfer of Accredited Certification of Management Systems), MD 5:2015 (Duration of QMS and EMS Audits).

C2-1.4 -> B2 BS OHSAS 18001: In accordance with the provisions of the Deutsche Akkreditierungsstelle (DAkkS), the "IAF Mandatory Document For Duration of QMS and EMS Audits" (IAF MD 5) also applies to the certification and auditing of occupational health and safety systems as per OHSAS 18001.

C2-1.5 -> B2 ISO 27001: ISO/IEC 27006



- C2-1.6 -> B2 ISO 22000: ISO 22003
- C2-1.7 -> B2 Food and feed standards: EN 45011 or ISO/IEC 17065 after coming into effect (not applicable for ISO 22000, Fami-QS and FSSC 22000).
- C2-1.8 -> B2 Certification as per the IFS International Featured Standards (including but not limited to IFS Food, IFS Logistics):

- TÜV SÜD MS is authorised by IFS Management GmbH) to conduct IFS audits and certifications. This authorisation lapses in the event the Framework Agreement ceases between IFS Management GmbH and TÜV SÜD Management Service GmbH;
- TÜV SÜD MS is obligated and irrevocably authorised by the client to transmit to IFS Management GmbH the relevant (detailed) results from the IFS audits and certifications, irrespective of the results of the audit; this data will be deposited there in an online database - the IFS portal;
- IFS Management GmbH is irrevocably authorized to make data on passed audits without detailed information available to food wholesalers and retailers via the online database.
- Clients themselves decide whether failed audits and the detailed results of passed and failed audits may be made available by IFS Management GmbH to wholesalers and retailers via the online database;
- IFS-certified companies are obliged to support audits carried out under the "IFS Integrity Program". Under the "IFS Integrity Program", the standard-setter IFS Management GmbH carries out activities in the field of complaints management and preventive actions to assure the quality of the IFS.

(1) Within the scope of complaints management, the IFS Management GmbH may conduct "investigation audits" which are aimed at managing and investigating complaints referring to completed IFS audits. Investigation audits are carried out either at short notice or unannounced by an auditor commissioned by IFS Management GmbH.



(2) Within the scope of preventive quality assurance activities, IFS Management GmbH conducts "surveillance audits" to monitor the quality of the completed IFS audits in a sampling approach regardless of whether or not a complaint has been made. The audits are selected at random and carried out by IFS Management GmbH.

(3) In re-approval witness audits, a standard certification audit carried out by an IFS auditor is attended by an auditor employed or commissioned by IFS Management GmbH.

If the measures performed under the Integrity Program reveal a breach in the implementation of the standard requirements on the part of the IFS-certified company, the company may be billed for the costs of additional audits performed under the Integrity Program.

C2-1.9 -> B2 Certification as per the GMP+ standard of GMP International:

Companies certified as per the GMP+-standard are permitted to use the GMP+-logo and must therefore strictly comply with the criteria defined by GMP+-International. Companies with a temporary acceptance are not permitted to use the GMP+-logo in any way.

Companies certified as per the GMP+-standard must cooperate in witness audits, parallel audits and additional audits (compliance audits, stricter supervision and repeat audits).

C2-1.10 -> B2 Certification as per the QS-Standard of QS Qualität und Sicherheit GmbH (Bonn, Germany):

Cooperation in witness audits: Q&S GmbH reserves the right to send an appointed person/organization to verify compliance with the certification standard. One way of verification is for Q&S GmbH and/or an auditor appointed by Q&S GmbH to perform a witness audit at the certified company.

Within the scope of QS certification, QS system participants are obliged to cooperate at all times in witness audits and monitoring audits performed by certification scheme owners, accreditation bodies and TÜV SÜD MS.



C2-1.11 -> B2 Certification as per GLOBALGAP:

Producers or companies certified as per GLOBALGAP must support audits carried out under the GLOBALGAP integrity program "Certification Integrity Programme, CIPRO". CIPRO audits are carried out by auditors commissioned by GLOBALGAP.

C2-1.12 -> B2 Certification in accordance with BRC Global Standard for Food Safety:

Surveillance of certified companies:

In justified cases, TÜV SÜD MS or BRC may carry out additional audits or question activities at any time at the expense of the certificate-holder to validate continued certification. These visits may take the form of announced or unannounced visits to undertake either a full or a partial audit.

Notification of the certification body:

In addition to the information duties in accordance with B2-4.2 of these Testing and Certification Regulations, the holder of the certificate is obliged to inform the certification body in writing without delay but within three working days at the latest (report to incident_food_feed_certification@tuev-sued.de) of any circumstances that may affect the validity of continuing certification. This includes particularly but not exclusively:

The legal proceedings with respect to product safety and legality

Product recalls

The certificate holder undertakes to provide TÜV SÜD MS with all information required to assess the effect on the validity of the current certificate.

C2-1.13 -> B2 Certification in accordance with BRC Packaging/BRC Global Standard for packaging and packaging materials:

In justified cases, TÜV SÜD MS or BRC may carry out additional audits or question activities at any time at the expense of the certificate-holder to validate continued certification. These visits may take the form of announced or unannounced visits to undertake either a full or a partial audit.



Notification of the certification body:

In addition to the information duties in accordance with B2-4.2 of these Testing and Certification Regulations, the certificate-holder is obliged to inform the certification body without delay in writing (report to incident_food_feed_certification@tuev-sued.de) of the circumstances affecting the validity of continued certification. This includes particularly but not exclusively:

- The legal proceedings with respect to product safety and legality
- Product recalls

The certificate holder undertakes to provide TÜV SÜD MS with all information required to assess the impact on the validity of the current certificate.

C2-1.14 -> B2 Certification in accordance with FSSC 22000

Surveillance of certified companies:

In justified cases, TÜV SÜD MS or Foundation for Food Safety Certification may carry out additional audits or question activities at any time at the expense of the certificate-holder to validate continued certification. These visits may take the form of announced or unannounced visits to undertake either a full or a partial audit.

Notification of the certification body:

In addition to the information duties in accordance with B2-4.2 of these Testing and Certification Regulations, the holder of the certificate is obliged to inform the certification body in writing without delay but within three working days at the latest (report to incident_food_feed_certification@tuev-sued.de) of any circumstances that may affect the validity of continuing certification. This includes particularly but not exclusively:

- The legal proceedings with respect to product safety and legality
- Product recalls

The certificate holder undertakes to provide TÜV SÜD MS with all information required to assess the effect on the validity of the current certificate.



C2-1.15 -> B2 Certification as per Fami-QS

Incident Management:

The certified company has the duty to inform TÜV SÜD MS about all incidents jeopardizing product safety and legality and, in the case of a product recall, in writing (report by means of "Fami-QS Notification Form D-CM-01.01" to: incident_food_feed_certification@tuev-sued.de) without delay but within two working days at the latest.

Special audits:

TÜV SÜD MS can carry out special audits at short notice, if the certified company is involved in an incident jeopardizing product safety and legality or is listed on the Fami-QS website as "under review"

Special rules:

Other applicable documents are the "rules for operators" (<http://www.fami-qs.org/documents.htm>).

C2-1.16 -> B2 Assessment of the fulfilment of relevant licensing requirements as a technical service (TS) of category C in the sense of the Framework Directive 2007/46/EC, of the ECE Convention of 1958 and the Road Traffic Licensing Regulations under the German Motor Transport Authority (KBA) type approval procedure:

TÜV SÜD MS is permitted to publish the names of KBA certificate holders. In certification procedures for the above mentioned regulations as well as for verification procedures, TÜV SÜD MS will inform the German Motor Transport Authority (Kraftfahrt-Bundesamt) about the issue, suspension, revocation, withdrawal and expiry of certificates, or other confirmations, that are always coupled with an existing ISO 9001-certificate and about confirmations of verification.



C2-1.17 -> B2 Verification as per StVZO (Regulations Authorizing the Use of Vehicles for Road Traffic), Article 19(3) including Annex XIX, and the directive governing the procedure and confirmation of quality system verification in the manufacturing of vehicle components for which component expert opinions are prepared:

Verification confirmations may only be used by manufacturers in connection with the appropriate component expert opinion as per Article 19 StVZO in conjunction with Annex XIX.

C2-1.18-> B2 Certification in accordance with the Accreditation and Approval Regulation for Employment Promotion (Zertifizierung nach Akkreditierungs- und Zulassungsverordnung Arbeitsförderung, AZAV): EN 45011 or, after coming into effect, ISO/IEC 17065.

In this context, the term "manufacturing facility" is also used for training venues. The period of validity for the certification of training providers is five years, or for the certification of training measures generally 3 years with the possibility of extending the period of validity to five years.

C2-1.19 -> B2 Payment Card Industry (PCI) Compliance Standards

The Client shall ensure that the employees in charge of the IT systems have been duly notified prior to carrying out the order.

The client shall provide all the necessary documentation and information to the employees of TÜV SÜD MS involved in carrying out the work. In the case of Onsite Reviews (Onsite Audits), this shall also include access to all premises required to carry out the review and the availability of individuals in charge during the review.

The current version of the "Payment Card Industry Standards" is binding and must be observed by the client. The same applies to notification obligations arising therefrom.

The client is obliged to back up data at least once a day so that data may be restored at reasonable expense in the event of data loss using automated processes.

TÜV SÜD MS hereby informs the client that activities such as Vulnerability Scans in particular - but not exclusively - carried out as part of the order may impair system operation or cause systems to crash and that such events cannot be ruled out. TÜV MS explicitly excludes any liability for damage or other consequences arising therefrom.



TÜV SÜD MS is not liable for the accuracy, completeness, operational procedures, temporal validity of, or changes in, the card organisations' security programmes and the assessment services based thereon. TÜV SÜD MS does not represent the client in the provision of the assessment service, nor does it assume liability

- for delays or losses,
- in the event of third-party claims,
- for the use and forwarding of assessment results based on the card organisations' security programmes and on the results of assessments carried out by the client.

The client irrevocably authorizes TÜV SÜD MS without requiring a separate declaration of consent from the Client, to retain the documentation and/or information produced or received as part of carrying out the order in accordance with the requirements of the card organisations or the PCI Security Standards Council, and to forward this documentation and/or information to the aforementioned parties on request.



Module C3) Special regulations for TUV SUD BABT (TÜV SÜD BABT) certification

(These terms and conditions supplement or amend modules A and B as follows:)

C3 -> A Module A

C3-1. -> A-1.3 the first paragraph is supplemented as follows: An order is deemed to be a completed TUV SUD BABT application form.

C3-2. -> A-1.3 The following provision is inserted as additional section A-1.11: The client undertakes to notify TUV SUD BABT without delay of all corrective actions and notices related to the safety of the supplied equipment associated with the design and/or production of the product in question concerning a product with the identification number CE 0168.

The client notifies TUV SUD BABT without delay of all reportable incidents concerning a product with the identification number CE 0168 which pose severe risk to public health or safety where the incident may have an impact to the certification of the device.

C3-3. -> A-2.6 The following provision is inserted as additional section A-2.6: Where a certificate is withdrawn without the holders consent TUV SUD BABT shall immediately advise the holder of the withdrawal.

C3-4 -> A-3.1 is appended by the following: A TUV SUD BABT certificate holder shall follow the rules and requirements for use of TUV SUD BABT Marks which detail these general testing and certification regulations.

C3 -> B1 Module B1

C3-5. -> B1-1.2 is replaced by the following: The client shall:

- provide technical documentation appropriate to the particular certification scheme to enable conformance of the samples with the standard to be assessed;
- at the request of Certification Body send or otherwise make available to TUV SUD BABT, free of charge, for the purpose of examination and testing, samples representative of the production envisaged for the certifiable product for which he has applied for a certificate.



Where TÜV SÜD BAPT is satisfied that all the requirements of the testing and certification regulations and the appropriate standard are met, TÜV SÜD BAPT will issue a certificate.

- Except where specified elsewhere in this document clauses B1-2.1 to B1-2.3, B1-2.5, B1-2.7 and B1-2.9.4 only apply to product certification that included the issue of a TSC certification mark (e. g. the BAPT approved and BAPT tick marks).



Module C4) Special Regulations for TÜV SÜD America Inc. (TÜV SÜD America) product testing and certification

(These terms and conditions supplement or amend modules A and B as follows:)

C4 -> A Module A

C4-1. -> A1.4 Insert after second paragraph: Clients may escalate appeals to the Standards Council of Canada (SCC) if they disagree with the appeal decision made by the TÜV SÜD America certification body regarding conformity with accreditation criteria for SCC accredited product certifications. The SCC is the final level of appeal.

C4 -> B Module B1

C4-2. -> B1-2.1 Replace with: In addition to a positive product testing result, the initial inspection of the manufacturing site must not raise any objections. A certificate entitling the holder to use a certification mark is not permitted until a first inspection procedure has been successfully completed. Continued use of the certification mark will depend on regular inspections (follow-up-service, see below).

C4-3. -> B1-2.10

The following provisions are inserted as additional section B1-2.10:

The following additional regulations apply for the US Environmental Protection Agency (EPA) ENERGY STAR® Program:

C4-3.1. -> B1-2.10.1

Testing results may be provided to the EPA

C4-3.2. -> B1-2.10.2

Certified products may be subject to verification. Costs associated with procurement, transfer and verification testing of the selected product are the sole responsibility of the certificate holder. Samples will be purchased from the open market unless otherwise arranged with TSC. If requested, the certificate holder shall provide at least three retail outlets where the product can be purchased "off the shelf". TSC reserves the right to arrange for verification testing at an EPA recognized testing laboratory of its choice. TSC personnel shall conduct or witness the testing if testing must be done at certificate holders manufacturing location.



C4-3.3. -> B1-2.10.3

The findings of testing may be challenged in accordance with the EPA ENERGY STAR® requirements. A representative sample will be re-tested at no charge to certificate holder with the results being reported to EPA. The certificate holder will be notified if a challenge is submitted.

C4-4. -> B1-2.11

The following provisions are inserted as additional section B1-2.11:

Special Regulations for product inspections (field evaluation)

C4-4.1. -> B1-2.11.1

The certificate/label holder must document any complaints in connection with inspected products and the correction of nonconformities. TSC must be immediately notified of any changes made to the products, recalls or safety related incidents and potential hazards after inspection.

C4-4.2. -> B1-2.11.2

The label is only valid for the individual product inspected and shall not be transferred to another product. The label is void if removed.

C4-4.3. -> B1-2.11.3

The Standards Council of Canada is the final level for appeals for Canadian product inspections.



Module C5) Special regulations for TÜV SÜD PSB Pte Ltd (TÜV SÜD PSB)

(These terms and conditions supplement or amend modules A and B as follows:)

C5 -> A Module A

C5-1. -> A-3.1 is supplemented by the following:

A TÜV SÜD PSB certificate holder shall follow the rules and requirements for use of any TÜV SÜD PSB certification marks which may detail these general testing and certification regulations.

C5 -> B1 Module B1

C5-2. -> B1-1.2 is replaced by the following:

The client shall provide any recent test reports, design and material specifications and all other relevant supporting documents together with the test order and the test samples.

C5 -> B2 Module B2

C5-3. -> B2-3.2.2

the last paragraph of B2-3.2.2 is replaced with the following:

If nonconformities become evident during the audit that are so serious that certificate award appears unrealistic even after reasonable corrective action, TSC shall inform the client of the nonconformities. The client has the option to terminate the certification audit. No refund of the certification fee will be given in the event of termination of the certification audit.



Module C6) Special regulations for TÜV SÜD South Asia

(These terms and conditions supplement or amend modules A and B as follows:)

C6 -> A Module A

C6-1. -> A-2.6 The following provision is inserted as additional section A-2.6:

The certificate can be suspended/terminated - if the certificate holder does not provide the appropriate corrective action and undergoes on-site correction for closure of major NCs - within 90 days from last day of onsite audit (Cert / Surveillance/repeat, etc.)

C6-2. -> A-1.4 Insert after second paragraph:

Clients may escalate appeals to the Social Accountability Accreditation services (SAAS) if they disagree with the appeal decision from the TÜV SÜD South Asia certification body regarding conformity with accreditation criteria.

C6-3 -> A-1.6 is appended by the following:

Accreditation body regulation demands to have witnessing of Certification body auditors on site. These are at times market surveillance visits by accreditation bodies. The selection of companies for witnessing is done by accreditation body or scheme owners. All certified and/or prospective clients for certification agree to cooperate with TUV SUD offices, in such activities as witnessed audits planned by Certification body/ accreditation body/ scheme owners or regulatory bodies, etc.

C6-4 -> A-3.3 is appended by the following which may detail these general testing and certification regulations:

Use of the certification mark for marketing purpose by certified client must be in line with TUV SUD South Asia procedure - TSSA_CCU_20 which is available at the certification body.



C6 -> B Module B

C6 -> B2 Module B2

C6-5 -> B2.1 is appended as follows:

The management systems audits are based on random sampling and the outcome of the audit is based on the quality of the samples selected. The audit does not absolve each site from ensuring that systems are followed in totality. The outcome of the audit is also not an indication that the quality of the work at each site and also all requirements at that site are followed in totality.

The number of auditor days and respective accreditation determinations cited in the quotation shall apply subject to the approval of the Certification Body.

C6-6 -> B2-3.2.1 is appended as follows:

Normally in all certification schemes, stage 1 audits are on-site; unless reviewed and agreed with certification body. In case of Food Safety Management system stage 1 audit - the review and evaluation of management system documentation is carried out necessarily onsite.

If nonconformities become evident during the audit that are so serious that certificate award appears unrealistic even after reasonable corrective action, TSC informs the client of the nonconformities and the client has the option to terminate the certification audit. No refund of the certification fee will be given in the event of termination of the certification audit.

For Business Social Compliance Initiative (BSCI):

The audits cycle is based on the BSCI guidelines. The audit planning and documentation reporting is done on BSCI Database. After initial audit based on the audit results, re-audit could be possible. The details could be obtained by contacting certification body or product managers.

For Worldwide Responsible Accredited Production (WRAP) :

The activities of certification body are limited to submission of report package to WRAP board for review. Certification (initial) audit or Follow up audits are possible in WRAP while the certificate decision is always taken by WRAP board for each audit. The details could be obtained by contacting certification body or product managers.



C6-8 -> B2-3.4 is appended as follows:

For Social Accountability Accreditation Services (SAAS) :

When the clients are certified under SA8000, normally the surveillance audits are 6 monthly – unless approved by certification body for annual surveillance program.

Minimum of one un-announced audit in any three year certification will be conducted. The second surveillance audit will be the mandatory unannounced audit. This audit can occur between 4-8 months, after the first surveillance.

Un-announced audits may be conducted additionally by certification body in case any Non conformity (or persistent issues) indicates the need for an additional unannounced audit during the period of certification. It shall be responsibility of certified client to extend cooperation during such surveillance activities by certification body.

Further, if the complaint is received from an interested party for non-compliance to SA8000 then investigation shall be undertaken and may be aided through the undertaking of an unannounced audit and interviews with outside stakeholders, such as: trade unions, NGOs, and the complainant, at a minimum. The investigation shall cover all elements identified in the complaint. In case an unannounced audit is carried out to investigate the compliant, the client shall bear all costs of such audit.

When SA8000 certification program is with 6 monthly surveillance audits then it is necessary to plan audits with 2 months in advance to avoid suspension.

In case of SA8000 audits a surveillance audit if not successfully executed 2 months before the Target Date leads to a suspension of the certificate.

C6-9 -> B2-3.6 is appended as follows:

The Certification Body makes information about issued, revoked or withdrawn certificates available to the public through website www.tuv-sud.in

For SA8000, such information is also made available by accreditation body SAAS through its website <http://www.saasaccreditation.org> .



Upon request from any interested party TÜV SÜD South Asia shall provide the information about the current status of the client after carrying out a suitable verification of the intent. The same shall be communicated to the client in advance. All other information, except for information that is made publicly available by the client, shall be considered confidential.

The clients shall be intimated before hand through an email / letter by the central certification unit if any confidential information is to be divulged to any external party.

C6-10 -> B2-4.6 The following provisions are inserted as additional section B2-4.6:

For integrated systems; the specific requirements of the individual systems must be identified and observed.

For ISO 9001 and ISO 14001:

Applicable mandatory documents are criteria of NABCB, documents of the International Accreditation Forum (IAF): MD01 (Certification of Multiple Sites Based on Sampling), MD02 (Transfer of Accredited Certification of Management Systems), MD05:2009 (Duration of QMS and EMS Audits) and other applicable documents, if any.

For BS OHSAS 18001:

In accordance with the criteria of National Accreditation Board for Certification Bodies (NABCB), the "IAF Mandatory Document For Duration of QMS and EMS Audits" (IAF MD 5) also applies to the certification and auditing of occupational health and safety systems as per OHSAS 18001

or ISO 27001:

Requirements of ISO/IEC 27006 and criteria of NABCB.

For ISO 22000:

Requirements of ISO 22003 and criteria of NABCB.

For Social Accountability Accreditation Services (SAAS):

Requirements of Procedure 200 and Procedure 201, SA8000 Guidance Document, advisories issued by SAAS time to time.



It shall be responsibility of certified clients or applicants to ensure the implementation of Advisories and/ or clarification or as such additional requirements issued by SAAS. The application documents for implementation at company are available at www.saasaccreditation.org.

For Business Social Compliance Initiative (BSCI):

Requirements of BSCI for certification bodies, SAAS Procedure 225, Memo and instructions issued by BSCI and/or SAAS time to time.

For Worldwide Responsible Accredited Production (WRAP):

Requirements of WRAP board for monitoring partners and its amendments if any.